Newmark *et al.*, U.S. Pat. No. 6,387,416 or Kuhrts, U.S. Pat. No. 6,475,530. Each of these rejections is discussed below.

Rejections under 35 U.S.C. § 112, second paragraph

The Examiner has rejected claims 1, 4, 7 and 19-21 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The second paragraph of Section 112 requires that the claims set out and circumscribe a particular area, which Applicants regard as their invention with a reasonable degree of precision and particularity. Specifically, the Examiner maintains that "[t]he claims are confusing since there is no person, animal, etc. to whom the composition is being administered." In response to this rejection, the claims have been amended to clarify that the composition is to be administered to a host in need thereof. Additionally, new claims have been added which specify preferred embodiments of the invention with respect to flavonoid dosage.

Rejections under 35 U.S.C. § 102

The Examiner has rejected claims 1, 4, 7 and 19-21 under 35 U.S.C. § 102 (a) as being anticipated by Nakajima *et al.* (2001) Planta Med 67:132-135, Krakauer *et al.* (2001) FEBS Letters 500:52-55, Kimura *et al.* (2001) Planta Med 67:331-334, Chi *et al.* (2001) Biochemical Pharmacology 61:1417-1427 or Chen *et al.* (2001) Biochemical Pharmacology 61:1195-1203; under 35 U.S.C. § 102(b) as being anticipated by Li *et al.* (2000) Immunopharmacology 49:295-306 or Meybeck U.S. Pat. No. 5,643,598; and under 35 U.S.C. § 102(e) as being anticipated by Xinxian, U.S. Pat. No. 6,290,995; Newmark *et al.*, U.S. Pat. No. 6,264,995; Newmark *et al.*, U.S. Pat. No. 6,391,346; Newmark *et al.*, U.S. Pat. No. 6,387,416 or Kuhrts, U.S. Pat. No. 6,475,530.

The Court of Appeals for the Federal Circuit has stated that anticipation requires the presence in a single prior art reference of each and every element of the claimed invention. Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick Co., 730 F.2d 1452, 1458 (Fed. Cir. 1984); Alco Standard Corp. v. Tennessee Valley Auth., 1 USPQ2d 1337, 1341 (Fed. Cir. 1986). "There must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field

of the invention." Scripps Clinic v. Genentech Inc., 18 USPQ2d 1001, 1010 (Fed. Cir. 1991, citations omitted). As explained in detail below, Applicant believes that the claims, as amended, are not anticipated by the prior art relied upon by the Examiner.

Rejections under 35 U.S.C. § 102(a)

The Examiner has rejected claims 1, 4, 7 and 19-21 under 35 U.S.C. § 102 (a) as being anticipated by Nakajima *et al.* (2001) Planta Med 67:132-135, Krakauer *et al.* (2001) FEBS Letters 500:52-55, Kimura *et al.* (2001) Planta Med 67:331-334, Chi *et al.* (2001) Biochemical Pharmacology 61:1417-1427 or Chen *et al.* (2001) Biochemical Pharmacology 61: 1417-1427. The Examiner provides that each of these references "teach that an extract from *Scutellaria baicalensis* is administered to a patient."

The Present Invention

The present invention relates generally to a method for the prevention and treatment of COX-2 mediated diseases and conditions. Claim 1, as amended, and new claim 24, are drawn to a method for inhibiting the COX-2 enzyme and claim 19, as amended, and new claim 28, are drawn to a method for inhibiting the COX-2 enzyme, wherein said inhibition results in a decrease of conditions and symptoms related to inflammation. As provided in the Specification, (page 4, lines 7-11), the COX-2 enzyme catalyzes two separate reactions: the metabolism of arachidonic acid to form the unstable prostaglandin G2 (PGG2), a cyclooxygenase reaction and the conversion of PGG2 to the endoperoxide PGH2, a peroxidase reaction. The short-lived PGH2 non-enzymatically degrades to PGE2. Prostaglandins, including PGE2, contribute to the pain and fever associated with inflammation.

Inflammation is a complicated biological process involving DNA, mRNA gene expression, different cells, proteins, mediators, enzymes, chemical components, and normal function of the microcardiovascular system and general immune functions. Using an inflammation animal model, croton oil induced mouse ear swelling, as an example, any agent which possesses any of the following mechanism of actions would yield anti-inflammatory output:

1. Croton oil absorption blocker;
2. Endothelial cells, leukocytes deactivator;
3. Cytokine production down regulator;
4. Histamine blocker;
5. Chemokines blocker;
6. Phospholipids A2 (PLA2) enzyme inhibitor;
7. PLA2 gene expression down regulator;
8. iNOS gene expression down regulator;
9. iNOS inhibitor;
10. Adhesion molecule expression inhibitor;
11. Adhesion molecule ligands;
12. Adhesion molecule receptor binder;
13. Lipoxygenase inhibitor;
14. Lipoxygenase gene down regulator;
15. Peroxidase inhibitor;
16. Free radical scavenging agent;
17. Prostaglandin E2 scavenging agent;
18. Cyclooxygenase gene down regulator; and
19. Cyclooxygenase inhibitor;

Essentially, any drugs, chemicals or natural products that interfere with any of the steps of the inflammation cascade may lead to the reduction in inflammation and can therefore be characterized as anti-inflammatory agents. Cyclooxygenase enzyme inhibitors block only the metabolism of arachidonic acid, which in turn leads to the decreasing of the production of the pain-associated mediators prostaglandins. The result of the administration of a COX inhibitor will be a lessening of the pain and vasodilation and as well as other symptoms related to inflammation.

The Nakajima *et al.* Reference

Nakajima *et al.* ((2001) Planta Med 67:132-135), teach the inhibition of the production of Eotaxin by free-B-ring flavonoids isolated from *Scutellaria baicalensis*. Specifically, four major flavonoids from *Scutellaria* root --baicalein, proxylin A, baicalin and skullcapflavon II-- were found to inhibit the production of eotaxin. Eotaxin is a protein produced by dermal fibroblasts in response to interleukin-4 and tumor necrosis factor-α and is related to bronchial diseases, such as allergies and asthma. This protein is not related to cyclooxygenase and has nothing to do with the metabolism of arachidonic acid. The inhibition of the production of eotaxin is completely unrelated to the inhibition of COX-2 activity. As noted above, independent claim 1, as amended, and new claim 24,

are drawn to a method for inhibiting the COX-2 enzyme and independent claim 19, as amended, and new claim 28, are drawn to a method for inhibiting the COX-2 enzyme, wherein said inhibition results in a decrease of conditions and symptoms related to inflammation. Additionally, claims 1 and 19, as amended, are drawn to administering a composition comprising a mixture of free-B-ring flavonoids. Therefore, Applicant maintains that the claims, which drawn to the inhibition of COX-2, are not anticipated by the Nakajima *et al.* Reference.

The Krakauer *et al.* Reference

Krakauer *et al.* ((2001) FEBS Letters 500:52-55), disclose the inhibition of various cytokines and chemokines, including IL-1β, IL-6, TNF-α, IFN-γ, MCP-1, MIP-1α and MIP-1β, by the free-B-ring flavonoid baicalin isolated from *Scutellaria baicalensis*. Cytokines and chemokines play an important role in the initiation of the inflammation process. Cytokines, of which there are about 60, regulate cell-cell communication between immune cells. They are small proteins that produce local and transient effects. Chemokines are chemotactic molecules that attract immune cells, helping them to "home" to sites of inflammation. Frequently, the cells producing these regulatory molecules also bear receptors for them, participating in a complex network of self-regulating and local interactions that orchestrate the proliferation of immune cells and then the subsequent decline of immune activity. COX mediated inflammation pathways are downstream biological responses. Inhibition of the production of cytokines and chemokines by free-B-ring flavonoids from *Scutellaria baicalensis* is unrelated to the inhibition of COX-2 activity. Therefore, Applicant maintains that the current claims, drawn to the inhibition of COX-2, by free-B-ring flavonoids or mixtures thereof, are not anticipated by the Krakauer *et al.* Reference.

The Kimura *et al.* Reference

Kimura *et al.* ((2001) Planta Med 67:331-334), disclose the inhibition of adhesion molecule expression by various free-B-ring flavonoids isolated from *Scutellaria baicalensis*. Specifically, the free-B-ring flavonoid baicalein was found to inhibit the expression of both ELAM-1 and ICAM-1. Adhesion molecules are proteins, unrelated to

both COX-2 activity and the arachidonic acid pathway. Therefore, for the reasons discussed above, Applicant maintains that the current claims, drawn to the inhibition of COX-2, are not anticipated by the Kimura *et al.* Reference.

The Chi *et al.* Reference

Chi *et al.* ((2001) Biochemical Pharmacology 61:1195-1203) demonstrate that wogonin, a free-B-ring flavonoid, inhibits nitric oxide (NO) as well as PGE2 production via suppression of the induction/gene expression of both iNOS and COX-2 in LPS-induced RAWcells (page, 1200, col. 1). It was also found that wogonin inhibited PGE2 production more potently than NO production. Gene expression is a measure of mRNA production from DNA. Gene expression down regulation does not necessarily lead to inhibition of the protein itself. Direct COX-2 enzyme inhibition by wogonin was not measured in this study; however, the authors speculated that in addition to the inhibition of the gene expression of COX-2, wogonin also inhibited the activity of the enzyme itself. The authors provided that although the reason for the various sensitivities to inhibition by wogonin was not known, "[i]t may be explained in part by the fact that, in addition to the suppressive effects of wogonin on iNOS and COX-2 induction, it also inhibited COX-2 activity from the homogenate of LPS-induced RAW 264.7 cells" (page 1200; col. 1). It is clear that Chi *et al.* are merely speculating that wogonin directly inhibits the COX-2 enzyme. There was no direct measurement of COX-2 enzyme inhibition activity of wogonin in Chi's report and it was expressly stated that the reason for the various sensitivities was not known. As there is no evidence to support this supposition, Chi *et al.* do not teach the inhibition of COX-2 by the free-B-ring flavonoid wogonin. Applicant maintains that the claims, as amended, are not anticipated by the Chi *et al.* reference.

The Chen *et al.* Reference

Chen *et al.* ((2001) Biochemical Pharmacology 61:1417-1427) examined three free-B-ring flavonoids: wogonin, baicalin and baicalein for their effects on LPS-induced NO production and iNOS and COX-2 gene expression. As noted above, gene expression is a measure of mRNA production from DNA and further, gene expression down

regulation does not necessarily lead to inhibition of the protein itself. In this study, Chen *et al.* also indirectly examined the effects of baicalin, baicalein and wogonin on iNOS and COX-2 enzyme activity, using a cell model of LPS stimulated prostaglandin E2 (PGE2) production, as described in Section 3.3 beginning on page 1420 of the reference. The authors conclude that "[w]ogonin, but not baicalin or baicalein, inhibited LPS-induced COX-2 expression." (Page 1426, col. 1). The authors also expressly provide that "[t]hese compounds [wogonin, baicalin and baicalein] did not affect iNOS and COX-2 (enzyme) activity." (Page 1426, col. 1). Thus, Chen *et al.* found no direct enzyme inhibition by any of the free-B-ring flavonoids evaluated. As noted above, the claims of the present invention are drawn to a method for inhibiting the COX-2 enzyme by compositions containing both a free-B-ring flavonoid (claims 24 and 28) and compositions containing mixtures thereof (claims 1 and 19). Thus, Chen *et al.* actually teach away from the method of the present invention and do therefore do not anticipated the claims.

Rejections under 35 U.S.C. § 102(b)

The Examiner has rejected claims 1, 4, 7 and 19-21 under 35 U.S.C. § 102(b) as being anticipated by Li *et al.* (2000) Immunopharmacology 49:295-306 or Meybeck U.S. Pat. No. 5,643,598. The Examiner provides that each of these references teach that an extract from *Scutellaria baicalensis* is administered to a patient. Each of these rejections is discussed below.

The Li *et al.* Reference

Li *et al.* ((2000) Immunopharmacology 49:295-306) teach the inhibition of the binding of a number of chemokines to human leukocytes or cells via selective binding to chemokine ligands by the free-B-ring flavonoid baicalin, isolated from *Scutellaria baicalensis*. As noted above, chemokines are chemotactic molecules that attract immune cells, helping them to "home" to sites of inflammation. Frequently, the cells producing these regulatory molecules also bear receptors for them, participating in a complex network of self-regulating and local interactions that orchestrate the proliferation of immune cells and the subsequent decline of immune activity. COX mediated

inflammation pathways are downstream biological responses. Inhibition of the binding of chemokines is unrelated to the arachidonic acid metabolism by COX-2. Applicant maintains therefore that the current claims, which are drawn to the inhibition of COX-2 by free-B-Ring flavonoids and mixtures thereof, are not anticipated by the Li *et al.* reference.

The Meybeck Reference

Meybeck (U.S. Pat. No. 5,643,598) teaches a method of formulating Scutellaria extracts or at least one active substance isolated from such extracts in liposomes for topical usage having anti-allergic, anti-inflammatory and anti-aging activity. A number of free-B-ring flavonoids, including wogonin, baicalein, scullcapflavone II and baicalin are characterized as antibacterial compounds, as described in the section entitled "Extraction and Isolation of the Antibacterial Components" (Specification, col. 6) and illustrated in Figure 2. With reference to Table II (Specification, col. 11-12), the *Scutellaria* extract in gel exhibited **no** anti-inflammatory effect (1.1%) when not incorporated into a liposome. Only the liposome formulated extract had a significant anti-inflammatory effect (69.6%). A moderate effect (30.7%) was observed from the empty liposome. Thus, the Meybeck reference actually teaches away from the method of this invention with respect to the anti-inflammatory activity of these compositions. Additionally, Meybeck neither teaches nor suggests the use of Free-B-ring flavonoids or mixtures thereof as COX-2 inhibitors, therefore Meybeck does not anticipate the claims of this invention, which are drawn to the inhibition of the COX-2 enzyme. Finally, the amount of free-B-ring flavonoid or mixtures thereof in the formulation taught by Meybeck is significantly less than the amount set forth in the claims, as amended. Meybeck claims a Scutellaria extract (alcoholic, aqueous or hydroalcoholic) formulated in a ratio of between 0.00001 to 2% by weight of the extract or any active substance contained in the extract, in an anti-inflammatory composition for topical applications. (Col. 6, lines 45-50). As amended, the claims of this invention are drawn to a composition comprising 10% to 100% of the free-B-ring flavonoid or mixtures thereof.

Rejections under 35 U.S.C. § 102 (e)

The Examiner has rejected claims 1, 4, 7 and 19-21 under 35 U.S.C. § 102(e) as being anticipated by Xinxian, U.S. Pat. No. 6,290,995; Newmark *et al.*, U.S. Pat. No. 6,264,995; Newmark *et al.*, U.S. Pat. No. 6,391,346; Newmark *et al.*, U.S. Pat. No. 6,387,416 or Kuhrts, U.S. Pat. No. 6,475,530. The Examiner reasons that each of these references teach that an extract from *Scutellaria baicalensis* is administered to a patient. Each of these rejections is discussed below.

The Xinxian Reference

Xinxian (U.S. Pat. No. 6,290,995) teaches a method for producing a pharmaceutical composition of baicalin for use in the treatment of cancer and control of cancer cells. Example 5 demonstrates that baicalin inhibits DNA synthesis of TPA-stimulated mouse epidermis and therefore prevents epidermis cancer (col. 6, lines 22-25). Example 6 demonstrates the effectiveness of baicalin in the treatment of gastric cancer. In this example, baicalin is shown to inhibit levels of DNA methylation, p^{53} mutations, ^{17}p allelic loss of cancer cells and increase the function of tumor suppressor of gastric cancer cells. Example 7 demonstrates that baicalin inhibits oncogenes and Example 8 demonstrates that baicalin inhibits tumor cell proliferation and prevents tumor incidence on an animal model *in vivo*. The Xinxian patent does not teach or suggest that the free-B-ring flavonoid, baicalin, isolated from *Scutellaria baicalensis* inhibits COX-2 activity. Applicant maintains therefore that the claims of this invention, which are drawn to the inhibition of COX-2 by free-B-Ring flavonoids and mixtures thereof, are not anticipated by the Xinxian patent.

The Newmark References

Newmark *et al.* (U.S. Pat. No. 6,264,995, the '995 patent), teach an herbal composition, which contains extracts from 13 different plants, including *Scutellaria baicalensis*. The patent provides that the extract reduces inflammation in bones and joints by inhibiting the COX-2 enzyme. The only definition of the *Scutellaria baicalensis* root extract is 5:1, which generally refers to 5 parts of plant root yielding one part of the extract. Considering that more than 58 compounds have been isolated from

Scutellaria baicalensis, a hydroalcoholic extract could contain any number of compounds including, but not limited to alkaloids, benzyl alcohol glycosides, lignans, benzopyranones, amino acids, phytosterols, monosugars, flavones and flavanones. The '995 patent does not teach or suggest the use of free-B-ring flavonoids or mixtures thereof as COX-2 inhibitors. Additionally, with reference to the Table provided in the patent (col. 12), the extract of *Scutellaria baicalensis* accounted for approximately 2.6% by weight of total weight of the formulation. As discussed in detail below, the amount of free-B-ring flavonoid or mixtures thereof in the formulation taught by Newmark *et al.* is significantly less than the amount set forth in the claims of the instant invention, as amended. Therefore, Newmark *et al.* does not anticipate the claims as amended.

In the roots of *Scutellaria baicalensis*, the baicalin content (which accounts for approximately 80% of the total free-B-ring flavonoid content) is approximately 10% of the weight of roots. If an average of 10% is used as a benchmark, one can obtain 10 grams of baicalin from 100 grams of dry root, assuming the extraction efficiency is 100%. With reference to the Table provided in the Newmark patent (col. 12), the *Scutellaria Baicalensis* root extract used in the formulation is a 5:1 extract, which means from 5 parts (grams/kilograms) of root, 1 part (grams/kilograms) of extract by weight is obtained. The Table further provides that the quantity of the extract used in the formulation is 20 mg. Thus, 100 mg of dry root was required to provide this amount of extract (20 mg x 5 = 100 mg dry root). Assuming for the sake of argument, that the maximum amount of baicalin/free-B-ring flavonoids was extracted, the baicalin content in the 20 mg of root extract would be approximately 10 mg. (100 mg root extract x 10% = 10 mg baicalin in the 20 mg of root extract). Thus, the maximum purity of baicalin in the 20 mg of extract is 50%. Thus, based on the information provided in the Table, the maximum % of baicalin in Newmark's formulation is 1.3% (10 mg/770 mg total dry weight). Finally, if 20 mg of a 5:1 extract (10 mg baicalin) is administered to an average weight adult at 75 kg (165 lb) body weight, the dosage range for the extract is 0.27 mg/kg (0.14 mg/kg for baicalin). As amended, the claims of this invention are now drawn to administering a free-B-ring flavonoid or mixture thereof wherein the content of said flavonoid or mixture thereof is 10% to 100%, and the dosage range is 2.0 to 200 mg/kg of body wieght Support for these amendments can be found in Tables 7 and 8 of the

Specification (pages 31 and 32) and the *in vivo* data illustrated in Example 9 and Figures 3 and 4.. Therefore, the Newmark *et al.* patent does not anticipate the claims, as amended.

Newmark *et al.* (U.S. Pat. No. 6,387,416), describe an orally or topically administered composition capable of reducing inflammation. With reference to the Table (Specification col. 8-9), the maximum % of baicalin in the formulation described in this patent is approximately the same as the '995 patent discussed above. (20 mg of a 5:1 extract/760 mg total). Additionally, as discussed above Newmark et al. neither teach nor suggest the use of free-B-ring flavonoids as COX-2 inhibitors. Therefore, based on the reasoning above, this patent does not anticipate the claims of this invention, as amended.

Newmark *et al.* (U.S. Pat. No. 6,391,346), describe an orally administered composition capable of reducing inflammation in animals. The composition contains 13 extracts, including an extract from the plant *Scutellaria baicalensis*. The only definition of the *Scutellaria baicalensis* root extract provided in the Specification is that it is 5:1, which as noted above, generally refers to 5 parts of plant roots yielding one part of the extract. Also as noted above, considering that more than 58 compounds have been isolated from *Scutellaria baicalensis*, a hydroalcoholic extract could contain any number of compounds including, but not limited to alkaloids, benzyl alcohol glycosides, lignans, benzopyranones, amino acids, phytosterols, monosugars, flavones and flavanones. Additionally, the patent does not teach or suggest the use of Free-B-ring flavonoids or mixtures thereof as COX-2 inhibitors. The extract from *Scutellaria baicalensis* accounted for approximately 12% to 18% by weight of total weight of the formulation. This amounts to a maximum of 6% to 9% by weight of free-B-ring flavonoids in the formulation. As discussed above, the claims have been amended to provide that the free-B-ring flavonoid or mixture thereof is present in an amount greater than 10%. Therefore, based on the above reasoning, this patent does not anticipate the claims of this invention, as amended.

The Kuhrts Reference

Kuhrts (U.S. Pat. No. 6,475,530) describe weight loss compositions that combine a weight loss effective compound and a botanical COX-2 inhibitor. The plant

"*Scutellaria baicalensis*" was referred to in the patent as a COX-2 inhibitor. There is no further description, however, of the material or extract of *Scutellaria baicalensis* being used. Nor is there any reference to amounts or dosage. "*Scutellaria baicalensis*" is the Latin name of a specific species of plant. As a commonly known that different parts of a plant contain totally different types of compounds in different concentrations. To date, there have been more than 58 compounds isolated from various parts of *Scutellaria baicalensis*. These compounds include alkaloids, benzyl alcohol glycosides, lignans, benzopyranones, amino acids, phytosterols, monosugars, flavones, and flavanones. The Kuhrts patent provides no examples to substantiate the claim of a COX inhibitor from *Scutellaria baicalensis*. Nor does the Kuhrts patent teach or suggest the use of free-B-ring flavonoids or mixtures thereof as COX-2 inhibitors. Therefore, Applicant maintains that the Kuhrts patent does not anticipate the claims of the instant invention.

Applicant believes that the pending claims are in condition for allowance. If it would be helpful to obtain favorable consideration of this case, the Examiner is encouraged to call and discuss this case with the undersigned.

This constitutes a request for any needed extension of time and an authorization to charge all fees therefore to deposit account No. 19-5117 if not otherwise specifically requested. The undersigned hereby authorizes the charge of any fees created by the filing of this document or any deficiency of fees submitted herewith to be charged to deposit account No. 19-5117.

Respectfully submitted,

Date: January 16, 2003

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Marked up version showing changes to claims under 37 C.F.R. § 1.121(c)(ii)

1. (twice amended) A method for inhibiting the cyclooxygenase enzyme COX-2 comprising administering to a host in need thereof a composition comprising 10% to 100% of [a Free-B-Ring flavonoid or a composition containing] a mixture of Free-B-Ring flavonoids; wherein said composition is isolated from a plant selected from the Labiatae family, the Scutellaria genus and the *Scutellaria baicalensis* species.

4. (twice amended) The method of claim 1 wherein said Free-B-Ring [flavonoid] flavonoids [or mixtures thereof] are isolated from a plant part.

19. (amended) A method for inhibiting the cyclooxygenase enzyme COX-2 comprising administering to a host in need thereof a composition comprising 10 % to 100% of [a Free-B-Ring flavonoid or a composition containing] a mixture of Free-B-Ring flavonoids; wherein said composition is isolated from a plant selected from the Labiatae family, the Scutellaria genus and the *Scutellaria baicalensis* species and wherein said inhibition results in reduced inflammation conditions and symptoms.

20. (amended) The method of claim 19 wherein said Free-B-Ring [flavonoid] flavonoids [or mixtures thereof] are isolated from a plant part.

22. (new) The method of claim 1 wherein the composition of Free-B-Ring flavonoids is administered in a dosage selected from 2.0 to 200 mg/kg of body weight.

23. (new) The method of claim 19 wherein the composition of Free-B-Ring flavonoids is administered in a dosage selected from 2.0 to 200 mg/kg of body weight.

24. (new) A method for inhibiting the cyclooxygenase enzyme COX-2 comprising administering to a host in need thereof a composition comprised of 10% to 100% of a Free-B-Ring flavonoid; wherein said composition is isolated from a plant

selected from the Labiatae family, the Scutellaria genus and the *Scutellaria baicalensis* species.

25. (new) The method of claim 24 wherein said Free-B-Ring flavonoid is isolated from a plant part.

26. (new) The method of claim 25 wherein the plant part is selected from the group consisting of stems, stem barks, twigs, tubers, roots, root barks, young shoots, seeds, rhizomes, flowers and other reproductive organs, leaves and other aerial parts.

27. (new) The method of claim 24 wherein the composition of Free-B-Ring flavonoid is administered in a dosage selected from 2.0 to 200 mg/kg of body weight.

28. (new) A method for inhibiting the cyclooxygenase enzyme COX-2 comprising administering to a host in need thereof a composition comprised of 10% to 100% of a Free-B-Ring flavonoid, wherein said composition is isolated from a plant selected from the Labiatae family, the Scutellaria genus and the *Scutellaria baicalensis* species and wherein said inhibition results in reduced inflammation conditions and symptoms.

29. (new) The method of claim 28 wherein said Free-B-Ring flavonoid is isolated from a plant part.

30. (new) The method of claim 29 wherein said plant part is selected from the group consisting of stems, stem barks, twigs, tubers, roots, root barks, young shoots, seeds, rhizomes, flowers and other reproductive organs, leaves and other aerial parts.

31. (new) The method of claim 28 wherein the composition of Free-B-Ring flavonoid is administered in a dosage selected from 2.0 to 200 mg/kg of body weight.